VERSION SHOWING CHANGES MADE

In the Specification:

On page 1, after line 1, insert:

--Cross-Reference to Related Applications

This application is the national phase application of International Application No. PCT/IB99/02053 filed July 30, 2001, entitled "Blood Separation System Particularly for Concentrating Hematopoietic Stem Cells." Priority is claimed to the PCT application filing date under 35 U.S.C. § 365.--

In the Claims:

1. (Amended) A system for the processing and separation of biological fluids into components, comprising a set of containers [(40,42-44)] for receiving the biological fluid to be separated and the separated components, and optionally one or more additional containers [(41)] for additive solutions, and a hollow centrifugal processing chamber [(20)] rotatable about an axis of rotation and having an axial inlet/outlet [(7)] for the biological fluid to be processed and for the processed components of the fluid, the processing chamber containing an axially movable member [(21)] which defines a separation space of variable size for receiving biological fluid, the member [(21)] being axially movable to intake a selected quantity of biological fluid to be processed into the separation space via said inlet and to express processed biological fluid components from the separation space via said outlet, and means [(60-69)] for monitoring the position of the axially movable member [(21)] to thereby control the amount of intaken biological fluid and the expression of separated components, the system further comprising a distribution valve arrangement [(45-48;120-127)] for establishing selective communication between the processing chamber [(20)] and selected containers [(40-44)] or for placing the processing chamber and containers out of communication, the system comprising means for controlling operation of the system in two operational modes, a separation mode and a non-separation transfer mode, wherein:

- in the separation mode fluids can be intaken into the processing chamber [(20)] while the chamber is rotating or stationary, fluid intaken into the chamber is centrifuged and separated into components, and the separated components expressed while the chamber is rotating or, optionally, for the last separated component, while the chamber is stationary; and

- in the transfer mode the processing chamber [(20)] intakes fluid and expresses fluid with the chamber stationary, the valve actuation arrangement [(45-48;120-127)] being actuable to transfer amounts of fluid from one container [(40-44)] to another via the processing chamber [(20)], by axially moving the member [(21)], without centrifugation or separation of the fluid into components,

and said means [(60-69)] for monitoring the position of the axially movable member [(21)] controls the amounts of non-separated fluids transferred.

2. (Amended) The system of claim 1, wherein the distribution valve arrangement comprises a set of rotational stopcock valves [(45-48)] arranged in a manifold array [(58)], or a multiport rotational valve [(120-132)].

3. (Amended) The system of claim 1 [or 2], wherein the distribution valve arrangement comprises a plurality of stopcock valves [(45-48)] connected to tubing lines interconnecting the set of containers [(40,42-44)], the optional additional containers [(41)], the processing chamber [(20)] and further stopcock valves, each stopcock valve [(45-48)] comprising a rotable stopcock valve member having a shaft [(84-87)] associated with drive means [(100-103)], [the rotation of] said shaft being rotatable to selectively connect[ing] or disconnect[ing] the stopcock valve's tubing lines.

4. (Amended) The system of claim 3, comprising means for allowing insertion of each stopcock valve [(45-48)] only in a defined angular alignment of the rotatable stopcock valve member.

5. (Amended) The system of claim 1 [or 2], wherein the distribution valve arrangement comprises a multiport valve comprising a central rotor [(127)] rotatably mounted in an annular stator [(126)], the rotor having a central port [(120)] connected to the processing chamber [(20)] and leading to the rotor outer periphery, and the stator having a plurality of ports [(121-125)] at selected angular locations each connected to a container [(40-44)] and each leading into the inner periphery of the annular stator, the central port [(120)] of the rotor being connectable to selected ports [(121-125)] of the stator [(126)], or disconnected, by rotation of the rotor [(127)].

6. (Amended) The system of [any preceding] claim 1, wherein the movable member is a piston [(21)] fluid-tightly movably mounted in a generally-cylindrical centrifugal processing chamber [(20)].

7. (Amended) The system of claim 6, further comprising optical means for monitoring the position of the piston [(21)], comprising an alignment of light emitting elements [(60)] generally parallel to the piston axis, and an alignment of light receiving elements [(61)] generally parallel to the piston axis, the receiving elements [(61)] being arranged to receive light from the emitting elements [(60)] transmitted through or past the piston [(21)] or reflected by the piston [(21)], and to deliver a signal [(62)] representative of the piston's position.

8. (Amended) The system of claim 7, wherein the receiving elements [(61)] are arranged to deliver said signal [(62)] to means [(70,71)] for moving the piston [(21)] and means [(60-65)] for controlling the piston's position.

9. (Amended) The system of [any preceding] claim 1, comprising an optical sensor [(83)] monitoring fluid in the tubing line [(51)] connected to the axial inlet/outlet [(7)], for stopping the intake of biological fluid when the tubing line [(51)] is empty during the intake mode and/or for providing a signal for switching the distribution valve arrangement [(45-48;120-127)] in the extraction mode.

10. (Amended) The system of [any preceding] claim 1, wherein the axial inlet/outlet comprises a rotatable seal [(3-6)] mountable in a stationary housing [(1-2)], said seal being operable for positive and negative pressure conditions in the rotatable chamber [(20)].

11. (Amended) The system of [any preceding] claim 1, wherein the processing chamber [(20)] is mounted for rotation about its axis by means of bearings [(9; 72, 73)] at opposite ends of the chamber, one end of the chamber [(20)] being associated with means [(55-57)] for rotating the chamber [(20)] by contacting the chamber's bottom [(22)] with a rotary disc [(55)] without any support at the chamber periphery.

12. (Amended) The system of [any preceding] claim 1, wherein the means for controlling operation of the system in said two operational modes comprises a microprocessor based control system controlling an automated protocol.

13. (Amended) A method of processing and separating biological fluids in a system according to [any preceding] claim 1, the method comprising:

separating a biological fluid with the system operating in the separation mode, by intaking fluid into the processing chamber [(20)] while the chamber is rotating or stationary, centrifuging fluid intaken into the chamber [(20)] to separate the fluid into components, and expressing the separated components while the chamber is rotating or possibly, for the last component, while the chamber is stationary; and

transferring fluid between containers [(40-44)] with the system operating in the transfer mode, by intaking fluid into the processing chamber [(20)] with the chamber stationary, actuating the valve distribution arrangement [(45-48;120-127)] to transfer an amount of fluid from one container [(40-44)] to another via the processing chamber [(20)], by moving the member [(21)], without centrifugation or separation of the fluid into components, and monitoring the position of the movable member [(21)] to control the amount of non-separated fluid transferred.

14. (Amended) The method of claim 13, wherein a component of the biological fluid is separated into a given container [(42)], the amount of said component separated into the given container [(42)] being controlled by monitoring the position of said member [(21)], and an additive solution is transferred from an additional container [(41)] to said given container [(42)] via the

processing chamber [(20)] in said transfer mode, the amount of additive solution transferred being calculated as a function of the amount of said separated component in the given container [(42)].

15. (Amended) The method of claim 13 [or 14], wherein a density gradient product and blood are introduced into the processing chamber [(20)], and a component of the biological fluid is separated into a given container [(42)] and its collection is completed when the density gradient appears.

16. (Amended) The method of [any one of claims] claim 13 [to 15], wherein operation of the system in said two operational modes is controlled according to an automated protocol by a microprocessor based control system.

17. (Amended) A disposable set for collecting and separating selected quantities of biological fluids comprising the centrifugal processing chamber [(20)] of a system according to [any one of claims] claim 1 [to 12], wherein the inlet/outlet of the centrifugal processing chamber [(20)] is connected to a container [(40)] of biological fluid, an additional container [(41)] containing an additive solution, a plurality of containers [(42-44)] for receiving the separated components of the biological fluid, interconnected by a distribution valve arrangement comprising a set of rotational stopcock valves [(45-48)] arranged in a manifold array [(58)], or a multiport rotational valve [(120-132)].

20. (Amended) [Use] A method comprising use of the system [of any one] of [claims] claim 1 [to 12], for processing variable volumes of biological fluid from 10 ml up to the maximum volume of the separation chamber [(20)], and for adding an additive solution to the separated components.

21. (Amended) [Use] The method according to claim 20, for separation of stem cells from blood and mixing the separated stem cells with a preservative solution.

22. (Amended) [Use] The method according to claim 21, for separation of hematopoietic stem cells from umbilical cord blood, from an apheresis collection, or from a bone marrow aspirate.

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Note on the correction of Fig. 2:

In addition to the corrections made during the international preliminary examination, references 72 and 73 (mentioned in claim 9) have been added to Fig. 2.

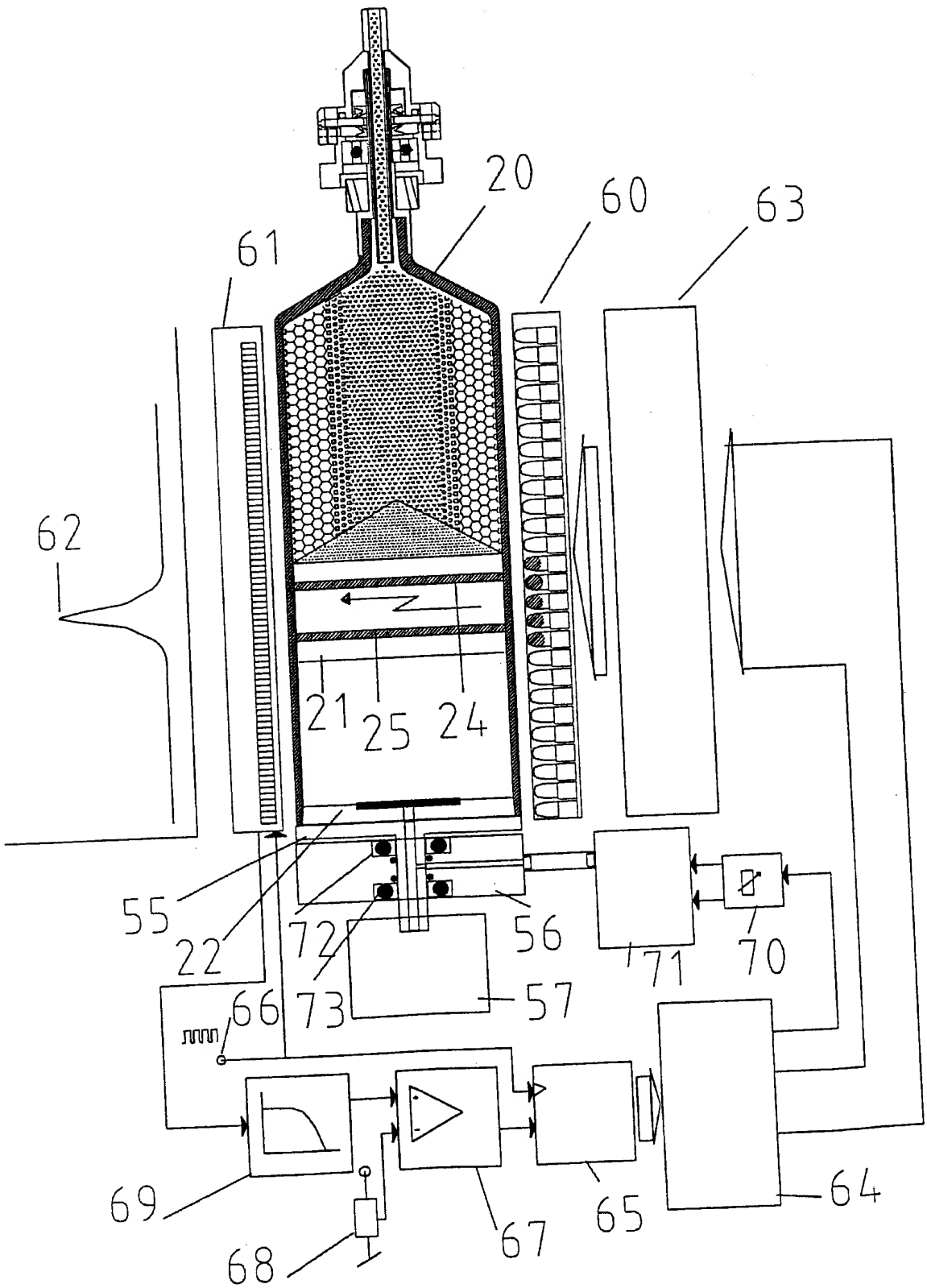

Fig. 2

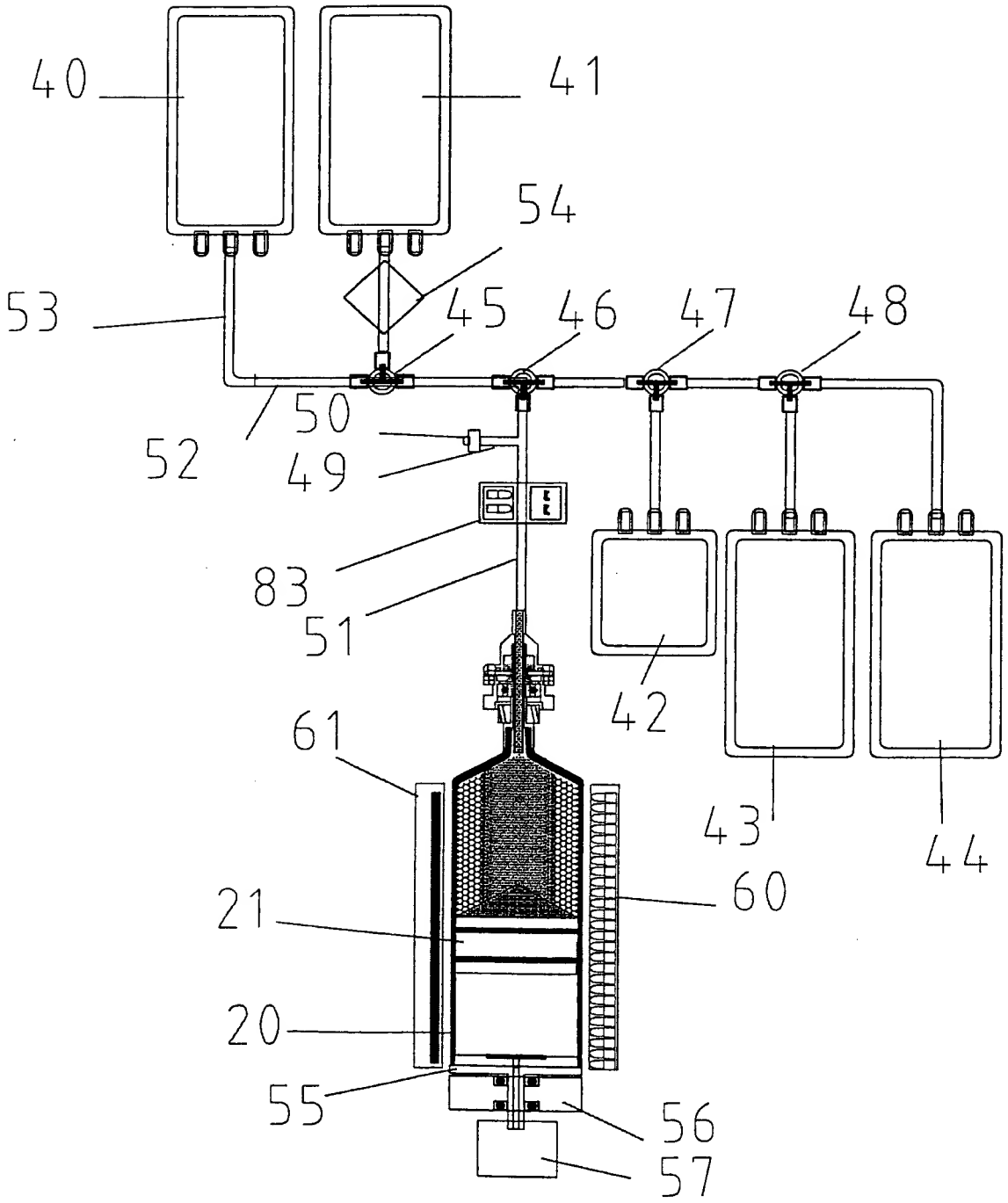

Fig. 3

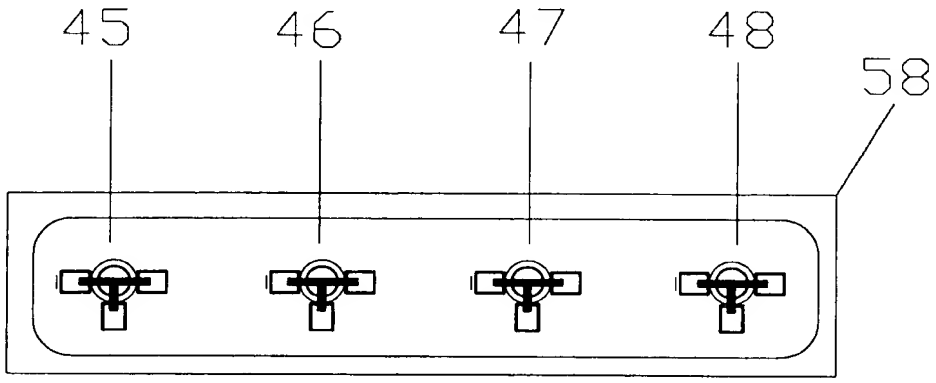
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Fig. 4

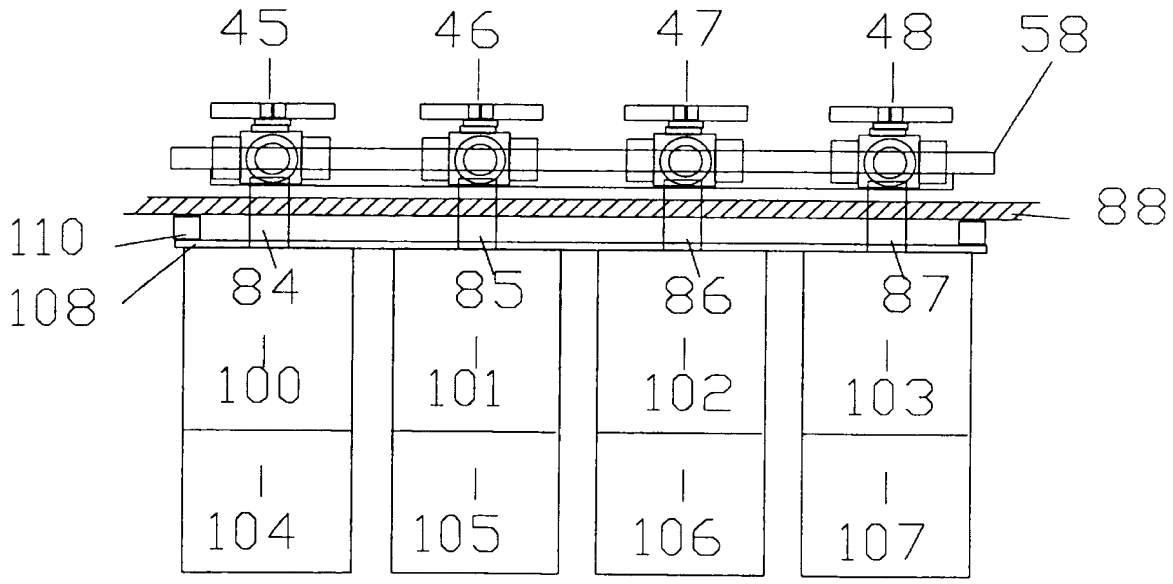
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Fig. 5